



[Document Identifier: HHS-OS 17371-30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

Action: Notice

Summary: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, will submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for extension of the approved information collection assigned OMB control number 0990-0294, scheduled to expire on September 30, 2012. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

Deadline: Comments on the ICR must be received within 30 days of the issuance of this notice.

Addresses: Submit your comments, including the OMB control number 0990-0294 and document identifier HHS-OS-17371-30D, to OIRA_submission@omb.eop.gov or via facsimile to (202) 395-5806. Copies of the supporting statement and any related forms may be requested via e-mail to Information.CollectionClearance@hhs.gov or by calling (202) 690-6162.

Information Collection Request Title: Standards for Privacy of Individually Identifiable Health Information and Supporting Regulations at 45 CFR Parts 160 and 164

Abstract: The Privacy Rule implements the privacy requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996. The regulations require covered entities (as defined in the regulations) to maintain strong protections for the privacy of individually identifiable health information; to use or disclose this information only as required or permitted by the Rule or with the express written authorization of the individual; to provide a notice of the entity's privacy practices; and to document compliance with the Rule. Respondents are health care

providers, health plans, and health care clearinghouses. The affected public includes individuals, public and private businesses, state and local governments.

Estimated Annualized Burden Table

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden - Hours

Section	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden (in hours) per Response	Total Burden Hours
160.204	Process for Requesting Exception Determinations (states or persons)	40	1	16	640
164.504	Uses and Disclosures—Organizational Requirements	764,799	1	5/60	63,733
164.508	Uses and Disclosures for Which Individual authorization is required	764,799	1	1	764,799
164.512	Uses and Disclosures for which Consent, Individual Authorization, or Opportunity to Agree or Object is Not Required	113,524	1	5/60	9,460

	(or other specified purposes by an IRB or privacy board)				
164.520	Notice of Privacy Practices for Protected Health Information (health plans)	10,570	1	3/60	529
164.520	Notice of Privacy Practices for Protected Health Information (health care providers—dissemination)	613,000,000	1	3/60	30,650,000
164.520	Notice of Privacy Practices for Protected Health Information (health care providers—acknowledgment)	613,000,000	1	3/60	30,650,000
164.522	Rights to Request Privacy Protection for Protected Health Information	150,000	1	3/60	7,500
164.524	Access of individuals to Protected Health Information (disclosures)	150,000	1	3/60	7,500
164.526	Amendment of Protected Health Information (requests)	150,000	1	3/60	7,500
164.526	Amendment of Protected Health Information (denials)	50,000	1	3/60	2,500
164.528	Accounting for Disclosures of Protected Health Information	1,080,000	1	5/60	90,000
Total					62,254,161

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Information Collection Clearance Officer

Department of Health and Human Services

Billing Code: 4153-01

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